IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAs) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
THIS DOCUMENT RELATES TO:	:	**MDL No. 3094**
ALL ACTIONS / ALL CASES	:	**2:24-md-03094-KSM**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER COMPLAINT

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INTRODUCTION

GLP-1RAs have been approved by the Food and Drug Administration ("FDA") and widely used for nearly two decades. *See* Master Complaint, Dkt. 294 (hereinafter "Complaint") ¶ 127. During that time, GLP-1RAs and GLP-1RA/GIPs have revolutionized the treatment of type 2 diabetes and obesity. These medicines are widely recognized for their safety and efficacy, which have been established in hundreds of studies and the treatment of millions of patients.

Plaintiffs' Complaint—and this litigation—focus principally on allegations that Novo Nordisk ("Novo") and Eli Lilly and Company ("Lilly") failed to adequately warn of certain side effects. This motion does not challenge the failure-to-warn allegations; Defendants will address them in their cross-cutting motions regarding preemption, adequacy of the warnings, and general causation (Issues 2 and 3). Instead, this motion seeks dismissal of various additional claims that Plaintiffs have tacked onto their Complaint that are extraneous to the core issues in the litigation, inadequately pleaded, or plainly foreclosed.[1]

In particular, Plaintiffs claim that Novo and Lilly deceived them or their physicians based on a compilation of unactionable marketing statements and irrelevant claims relating to advertising with prescribing physicians. Plaintiffs fail to translate these broad allegations into viable causes of action for fraud or breach of warranty. Plaintiffs' challenge to these medications' FDA-approved design and formulation is also preempted by federal law and insufficiently pleaded. This Court should therefore dismiss the following claims:

Express Warranty (Count III): The Court should dismiss the express warranty claims under all state laws because generalized statements that a medicine is "safe" and "effective" do

[1] The motion focuses on cross-cutting deficiencies in the pleading and leaves for subsequent stages in the litigation state-by-state issues and issues related to particular injuries.

not create an express warranty, nor do omission claims. And, in many states, express warranty claims are barred by the intercession of prescribing physicians as learned intermediaries.

Implied Warranty (Count IV): Plaintiffs manage to plead even fewer facts to support their implied warranty claims, which face significant hurdles under state law. Many courts reject implied warranties altogether for product liability cases. Other courts reject implied warranties specifically for prescription medications because a physician stands between the manufacturer and the patient. Plaintiffs have brought a personal injury tort action, not a contractual Uniform Commercial Code ("U.C.C.") action. The Complaint does not plead plausible claims for implied warranty.

Fraud and Misrepresentation Claims (Counts V-X): The Court should dismiss Plaintiffs' fraud and misrepresentation claims for failure to satisfy Rule 9(b)'s heightened pleading standard. Courts frequently dismiss fraud-based claims in the pharmaceutical context where, as here, the plaintiffs' conclusory allegations claim only that the defendant generally misrepresented the product as safe and effective. To the extent any remaining misrepresentation claims are not subject to Rule 9(b), they should still be dismissed because Plaintiffs have not identified actionable misstatements or omissions by Novo or Lilly.

Design Defect (Counts XI and XII): Plaintiffs' design-defect claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). This preemption argument is a pure legal issue that is distinct from the preemption argument regarding Plaintiffs' failure-to-warn claims, which will be the subject of a future summary-judgment motion. *See* Dkt. No. 282, CMO No. 20. Specifically, the design-defect claims turn on the allegation that Defendants should have designed GLP-1RAs and GLP-1RA/GIPs in a different and safer manner. But FDA regulations prohibit Defendants from making any "major changes" to prescription medicines—including any changes

to their formulation or active ingredients—without FDA's express prior approval. Thus, Plaintiffs' design-defect claims are preempted. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623-24 (2011).

Negligence (Count XIII): Plaintiffs' negligence claim repackages their failure-to-warn and design-defect claims, but also includes a string of conclusory allegations and a kitchen-sink of negligence theories that fail to state a claim. Because Plaintiffs do not plead this count with any level of detail and it duplicates the earlier failure-to-warn counts, the Court should dismiss this redundant and barebones claim.

Negligent Undertaking (Count XIV): Plaintiffs bring a claim for negligent undertaking in an inadequate attempt to plead around the learned intermediary doctrine. This count should be dismissed because courts have rejected negligent undertaking in the context of prescription medicines and Plaintiffs do not plead the generally recognized elements for such a claim even if one were recognized in this context.

Other Pleading Deficiencies: Although product liability actions in nearly half of the states are governed by statutory product liability acts, Plaintiffs fail to plead these claims. Instead, Plaintiffs repeat their "intent" to bring such claims sixteen times within other counts, including causes of action that several product liability acts preclude, such as implied warranty. Moreover, the Complaint fails to acknowledge the impact of product liability acts, including that they are the exclusive vehicle under which to file a product liability action in many states. This failure impacts approximately one-third of the current docket, and Defendants offer below case management solutions to clarify the claims Plaintiffs are filing.

The Court should dismiss Plaintiffs' demand for medical monitoring damages because it is not supported by well-pleaded facts.

Finally, under Rule 12(f), the Court should strike the statements that suggest the Complaint is non-operative. In their Preliminary Statement, Plaintiffs inject confusion into this proceeding by purporting to limit the effect of the Complaint. To be clear, this Court's Case Management Orders will govern the effect of the Complaint and any Short Form Complaints that may follow.

BACKGROUND

The safety profile of GLP-1RAs and GLP-1RA/GIPs has been well established in hundreds of clinical trials, large-scale observational studies, and two decades of real-world use. Like all medicines, GLP-1RAs and GLP-1RA/GIPs have certain side effects. The most widely reported risks are gastrointestinal symptoms (*e.g.*, nausea, vomiting, abdominal pain, etc.), which have been recognized in the medical and scientific communities for many years, including in treatment guidelines, review articles, and textbooks relied on by healthcare professionals. The known risks associated with GLP-1RAs and GLP-1RA/GIPs are reflected in their FDA-approved product labels, which, collectively, FDA has reviewed more than 60 times.

This motion to dismiss takes as true Plaintiffs' well-pleaded factual assertions and provides context from relevant product labeling and other judicially noticeable sources.

I. Defendants' GLP-1RA and GLP-1RA/GIP Medicines.

A. Novo's Semaglutide and Liraglutide Medicines.[2]

Ozempic® (semaglutide) is a once-weekly injectable formulation of semaglutide that FDA first approved in 2017 for improved glycemic control in adults with type 2 diabetes. Ex. A, at 1. In 2020, FDA approved an additional indication for reduction of risk of major adverse

[2] On a motion to dismiss, the Court may consider documents that are "integral to or explicitly relied upon in the complaint" without converting the motion to dismiss into one for summary judgment. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation marks omitted). Defendants are contemporaneously filing a Request for Judicial Notice that attaches the exhibits cited in this brief.

cardiovascular events in adults with type 2 diabetes and established cardiovascular disease. *See id.*

Wegovy® (semaglutide) is a once-weekly injectable formulation of semaglutide approved by FDA in 2021 for chronic weight management in adults. Ex. B, at 1. In 2024, FDA approved a second indication for reduction of risk of major adverse cardiovascular events in patients with established cardiovascular disease. *Id.* Wegovy® is the first and only FDA-approved obesity medicine that has been shown to reduce the risk of obesity-related complications, such as heart attack, stroke, and death. *Id.*

Rybelsus® (semaglutide) is the first and only FDA-approved oral GLP-1 medicine. *See* Ex. C, at 1. Rybelsus® has been FDA-approved since 2019 for the treatment of type 2 diabetes in adults and offers patients an alternative to an injection. *See id.*

Victoza® (liraglutide) is a once-daily injectable formulation of liraglutide that FDA first approved in 2010 for the treatment of type 2 diabetes in adults. Ex. D, at 1. In 2017, FDA similarly approved an additional indication for reduction of risk of cardiovascular complications in patients with type 2 diabetes and established cardiovascular disease. *See id.*

Saxenda® (liraglutide) is a once-daily injectable formulation of liraglutide first approved by FDA in 2014 for chronic weight management in adults. Ex. E, at 1.

B. Lilly's Dulaglutide and Tirzepatide Medicines.

Trulicity® (dulaglutide) was the first injectable GLP-1RA medication requiring once-weekly dosing through a pre-filled pen delivery device and is FDA-approved to treat type 2 diabetes. Ex. F, at 1. In 2020, Trulicity® was approved by the FDA to reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes. *See id.*

Mounjaro® (tirzepatide) was approved by the FDA in 2022 as a once-weekly injectable medicine for the treatment of type 2 diabetes. Ex. G, at 1. Mounjaro® is a dual-agonist, activating

the GLP-1 receptor and the glucose-dependent insulinotropic polypeptide ("GIP") hormone receptor. *See id.*

Zepbound® (tirzepatide) was approved by FDA in November 2023 for chronic weight management in adults. Ex. G, at 1. In December 2024, the FDA approved Zepbound® as the first prescription medicine approved to treat moderate to severe obstructive sleep apnea in adults with obesity. At this time, no lawsuits in this MDL involve Plaintiffs who allegedly used Zepbound®.

II. The MDL's Focus and the Complaint.

A. Plaintiffs' Alleged Misstatements and Omissions.

The Complaint focuses on alleged failure to warn that certain GLP-1RA and GLP-1RA/GIP medicines can cause side effects, including "gastroparesis," ileus/intestinal obstruction, gallbladder injury, non-specific gastrointestinal symptoms, and consequences of weight loss. Plaintiffs allege, for example, that Defendants "downplayed the nature, duration, extent and seriousness of gastrointestinal events and failed to warn about other adverse events." Compl. ¶ 4; *see also id.* ("Defendants have never provided adequate warnings[.]"); *id.* ¶ 10 ("Plaintiffs would not have taken GLP-1 RAs if they had been provided a full and clear warning of the true risks of taking these drugs."); Dkt. No. 235, CMO 18, at ¶ 11 ("Plaintiffs raise numerous claims related to the adequacy of Defendants' labels[.]").

Plaintiffs allege that Defendants overstated the weight loss benefits of their GLP-1RAs and GLP-1RA/GIPs. Compl. ¶¶ 9, 588, 590. They also claim these medicines do lead to weight loss, but assert such weight loss is, in some instances, "unhealthy" and caused some unspecified patients to lose muscle mass. *Id.* ¶¶ 96-106, 603. Plaintiffs also claim that Defendants failed to inform patients of a need for dietary counseling and guidance or failed to disclose that patients should remain on GLP-1RAs and GLP-1RA/GIPs to sustain weight, both issues that bear minimal

relevance to the causes of action pleaded in the Complaint. *Id.* ¶¶ 9, 84, 85, 308, 590, 592, 854, 855.

B. The Court Prioritized Early Resolution of Core Warning and Causation Issues.

After extensive briefing and argument, the Court issued a series of Case Management Orders prioritizing discovery and resolution of cross-cutting threshold issues regarding whether the failure-to-warn claims are preempted, whether the FDA-approved warnings were adequate as a matter of law, and whether there is sufficient reliable scientific evidence that the medicines at issue are even capable of causing some of the alleged injuries in the first place. As to the warnings issues (Issue 2), "[b]ecause issues related to the adequacy of each drug's label and the applicability of the preemption doctrine are likely to affect most cases, if not every case, in this MDL, and a ruling on these issues is likely to streamline the litigation, the Court [determined] this is a cross cutting issue worthy of early resolution." CMO 18, at ¶ 14. And as to general causation (Issue 3), the parties "agreed that early discovery and motion practice should occur simultaneously." CMO 20, at 1 n.1.

Thus, this cross-cutting motion to dismiss is filed in parallel with discovery on Issues 1, 2, and 3 in an effort to focus the proceeding on claims that are supported by the minimum required factual pleadings.

LEGAL STANDARD

A district court must dismiss claims that fail to state a claim upon which relief may be granted. *See* Fed. R. Civ. P. 12(b)(6). When evaluating the sufficiency of a complaint, factual allegations are scrutinized to determine if they are plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 683 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at

678. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. *Lutz v. Portfolio Recovery Associates, LLC*, 49 F.4th 323, 327 (3d Cir. 2022). First, the court identifies the elements needed to set forth a particular claim. *Id*. Second, the court should identify conclusory allegations, such as legal conclusions, that are not entitled to the presumption of truth. *See id.* Third, with respect to well-pled factual allegations, the court should accept those allegations as true and construe reasonable inferences in the plaintiff's favor. *Id.* at 328. The court must disregard legal conclusions and conclusory statements in the complaint. *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012). When alleging fraud, "a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

ARGUMENT

I. Plaintiffs Fail to Plead a Plausible Claim for Express Warranty (Count III).

In Count III, Plaintiffs repackage their core allegation that Defendants failed to warn about alleged side effects as a "breach of express warranty" claim. Plaintiffs assert that Defendants represented their products as "safe" by way of "labels, websites, advertisements, promotional materials and through other statements." Compl. ¶¶ 686-87. These claims fail for three reasons. *First*, as the Third Circuit has found, the label on a prescription medication contains a number of statements, as required by FDA, that preclude finding "safe and effective" to be an express warranty. *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig. (D'Apuzzo)*, 588 F. App'x 171, 175-76 (3d Cir. 2014) (non-precedential) (applying New Jersey law). *Second*, and related, the U.C.C. provides that statements of opinion, including statements like "safe and effective," do not constitute express warranties, and Louisiana courts agree as a matter of state law. *Third*, the failure to make a statement cannot be an express warranty. Plaintiffs' express warranty claims should be

dismissed, as they were in the first of these cases to be filed. *See Bjorklund v. Novo Nordisk A/S*, 705 F. Supp. 3d 636, 641-43 (W.D. La. 2023).

A. Representing an FDA-Approved Product as Safe and Effective Is Not an Express Warranty.

In *Avandia*, the Third Circuit found as a matter of law that plaintiffs could not state a claim for breach of express warranty that challenges a medication label's representation that it was "safe and effective," where that phrase was accompanied by the "contraindications, risk factors, and potential side effects" that must appear in any FDA-approved label. *See Avandia*, 588 F. App'x at 174. It makes no more sense to hold that FDA-approved materials are an "express warranty" than to hold that they can constitute "misrepresentations." *See* Section III.

In the Complaint here, Plaintiffs "incorporate by reference" 683 paragraphs of sometimes repetitive, sometimes irrelevant material, but the only specific representation that they characterize as an express warranty is in a single paragraph: "Defendants expressly represented to Plaintiffs and Plaintiffs' prescribing physicians that their GLP-1 RA Products were safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus, and/or to aid in chronic weight management." Compl. ¶ 686. Under a straightforward application of *Avandia*, that simple assertion, accompanied by many other qualifications, cannot support an express warranty claim. *See Avandia*, 588 F. App'x at 175.

B. Under the U.C.C., Opinions Are Not Express Warranties.

The U.C.C., which all states besides Louisiana have adopted, provides that an opinion or commendation "does not create a warranty." U.C.C. § 2-313; *Pennzoil Co. v. FERC*, 789 F.2d 1128, 1142 (5th Cir. 1986). Section 2-313 describes express warranties as affirmations of fact or promises about the goods, but not "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods." U.C.C. § 2-313. The

U.C.C. expressly provides that an opinion or commendation "does not create a warranty." *Id.* The statement attributed to Defendants in Paragraph 686—that the products are "safe"—is precisely the sort of opinion that does not constitute a warranty. *See*, *e.g.*, *Avandia*, 588 F. App'x at 175-78 (construing New Jersey law by reference to Ohio and Connecticut U.C.C. cases); *Barrett v. Tri-Coast Pharm., Inc.*, 518 F. Supp. 3d 810, 829 (D.N.J. 2021).

Indeed, with prescription medicines in particular, a plaintiff must identify the specific details of a purported promise. *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) ("[A]sserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty," particularly in the pharmaceutical context.), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *Horsmon v. Zimmer Holdings, Inc.*, No. 11-CV-1050, 2011 WL 5509420, at *4 (W.D. Pa. Nov. 10, 2011) (dismissing express warranty claim where "Plaintiff has not alleged any particular 'affirmation of fact or promise,' 13 Pa.C.S. § 2313(a), that would give rise to a reasonable inference that Defendants 'expressly warranted' that its products 'were safe, effective, fit, and proper for the use for which they were intended'").[3]

Plaintiffs fail to allege such details here, citing generalized statements of safety and efficacy in promotional materials that are nothing more than announcements of general opinion—not express warranties.

[3] Louisiana law also does not recognize an express warranty based on terms like "safe," "suitable" and "effective." *Bjorklund*, 705 F. Supp. 3d at 641-42. In any event, courts have required plaintiffs to identify whether and how their states' law departs from the generally applicable U.C.C. rule barring such claims. *See Pennzoil Co. v. FERC*, 645 F.2d 360, 387 (5th Cir. 1981); *see also Guardian Life Ins. Co. v. Weisman*, 223 F.3d 229, 231-32 (3d Cir. 2000) (noting and following the general practice of using cases from other jurisdictions and the plain language of the U.C.C. where there is no specific holding to the contrary).

C. Omissions Are Not Express Warranties.

A corollary to the U.C.C.'s requirement that an affirmation be specific is that omissions do not establish an express warranty. Plaintiffs' averments that Defendants "failed to warn," *see* Compl. ¶¶ 699-701, are only warranties by omission," which cannot be reconciled with the U.C.C. definition of express warranty. *Avandia*, 588 F. App'x at 178 ("[F]ail[ure] to disclose or understate[] known [health] risks that rendered [the product] potentially dangerous" cannot survive under the U.C.C.'s strict parameters for express warranties.); *Sidco Prods. Mktg., Inc. v. Gulf Oil Corp.*, 858 F.2d 1095, 1099 (5th Cir. 1988) ("Omissions, however, are not affirmative representations of any sort and thus cannot support a warranty claim, because express warranties must be explicit."). Thus, what Defendants did not say cannot be a basis for Plaintiffs' express warranty claim.

Plaintiffs' express warranty claims thus fail as a matter of law and should be dismissed.

II. Plaintiffs Fail to Plead a Claim for Breach of Implied Warranty (Count IV).

Plaintiffs' claims for breach of implied warranty fail because courts regularly recognize that such claims cannot be sustained for prescription products. Although jurisdictions vary as to ***why***, there is agreement that implied warranty claims cannot be brought against prescription medication manufacturers under the present circumstances.

Like express warranties, implied warranties are governed by the U.C.C. Section 2-314 governs the implied warranty of merchantability and provides that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." U.C.C. § 2-314. It then explains what merchantability is, generally summarizing the concept as conformity to other goods sold as such. *Id*. In this case, Plaintiffs have not alleged that any specific GLP-1RAs or GLP-1RA/GIPs are commercially inferior to another. Compl. ¶ 1 ("GLP-1 RA Products, including but not limited to . . . ."). Accordingly, it

cannot be the case that Defendants' products failed to conform to the commercial standard for the relevant class of goods.

Nor can Plaintiffs maintain a claim by invoking the implied warranty of fitness. Section 2-315 of the U.C.C. provides that the warranty applies "[w]here the seller at the time of contracting has reason to know any ***particular purpose*** for which the goods are required and ***that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods***." U.C.C. § 2-315 (emphasis added). Importantly, the buyer's "particular purpose must differ from the usual and ordinary use of the goods." *Moreno v. Allison Med., Inc.*, No. 20-CV-300, 2022 WL 3702061, at *8 (S.D. Tex. Aug. 9, 2022) (internal quotation marks omitted). Here, Plaintiffs do not allege that they had a unique purpose for the products they purchased. On top of that, they were prescribed specific GLP-1RAs and GLP-1RA/GIPs by their ***physicians***, not the manufacturers. *See id.* at *8-9 (explaining that the seller must know the buyer had a "particular purpose," which must be different from the ordinary and usual use, and the buyer must have relied on the seller's judgment); *Schomer v. Ethicon, Inc*., No. 12-CV-1497, 2017 WL 1028581, at *2 (S.D.W.V. Mar. 16, 2017) (applying Illinois law).

In some jurisdictions, there is no need even to consider the U.C.C. because implied warranty claims are subsumed by either the state's Product Liability Act or a non-statutory strict liability cause of action. That is true for Louisiana, the single non-U.C.C. jurisdiction. *See Waguespack v. Pliva USA, Inc.*, No. 10-CV-692, 2010 WL 2086882, at *1 (E.D. La. May 24, 2010) (dismissing plaintiff's claims in a prescription drug case, including breach of implied warranty, which did not arise under the Louisiana Product Liability Act). It also is true in Connecticut, Indiana, Kansas, Minnesota, Mississippi, Nebraska, New Jersey, and Ohio. *See, e.g.*, *Collazo v. Nutribullet*, 473 F. Supp. 3d 49, 51-52 (D. Conn. 2020); *Kapps v. Biosense Webster,*

Inc., 813 F. Supp. 2d 1128, 1162 (D. Minn. 2011); *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 686-87 (S.D. Miss. 2019); *Thelen v. Somatics, LLC*, No. 20-CV-1724, 2021 WL 1215006, at *2 (M.D. Fla. Mar. 31, 2021) (applying Nebraska law); *Simpson v. DePuy Synthes Sales, Inc.*, No. 19-CV-9062, 2019 WL 11679465, at *2 (D.N.J. Dec. 31, 2019); *Groeschen v. Alcon Laby's, Inc.*, No. A 2300825, 2024 Ohio Misc. LEXIS 2, at *11 (Ohio Ct. Com. Pl. Feb. 2, 2024).

Other states foreclose implied warranty given the role of the prescribing physician, which destroys privity or results in the claim being barred under the learned intermediary doctrine. These include Florida, Georgia, Kentucky, North Carolina, and Pennsylvania. *See, e.g.*, *Dimieri v. Medicis Pharms. Corp.*, No. 14-CV-176, 2014 WL 3417364, at *6 (M.D. Fla. July 14, 2014); *Wheeler v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 1344, 1354 (S.D. Ga. 2013); *Estate of Demoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 882 (W.D. Ky. 2017); *Johnson v. Smith & Nephew, Inc.*, 621 F. Supp. 3d 593, 600-01 (W.D.N.C. 2022); *Makripodis ex rel. Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987).

And, of course, other states require privity for breach of implied warranty claims in general. *See Curl v. Volkswagen of Am., Inc.*, 871 N.E.2d 1141, 1147-48 (Ohio 2007) (observing that a "significant number of states retain privity requirements in some form for parties asserting claims of breach of implied warranty," and collecting cases).

Even if these were claims that could be brought under a state law, Plaintiffs' implied warranty claims fail because they contain no more than conclusory statements, alleging "Defendants impliedly warranted to Plaintiffs, Plaintiffs' prescribing physicians, and the medical community that Defendants' GLP-1 RA Products were of merchantable quality and safe and fit for their ordinary purpose." Compl. ¶ 711. Plaintiffs provide no added detail about the facts that

underlie these supposed implied warranties except to allude to their failure to warn claims: "Defendants' . . . GLP-1 RA Products did not conform to Defendants' implied warranties and were unfit for their ordinary purposes because Defendants failed to provide adequate warnings." *Id.* ¶ 714.

For those states where an implied warranty claim might proceed, Plaintiffs needed to identify all of the elements of whichever implied warranty they are asserting, not merely repeat the label of each warranty in a conclusory sentence. *See Sweda v. Univ. of Pa.*, 923 F.3d 320, 338 (3d Cir. 2019), *abrogated on other grounds as stated in Mator v. Wesco Distrib.*, 102 F.4th 172, 184 n.3 (3d Cir. 2024).

Accordingly, the Court should dismiss Plaintiffs' breach of implied warranty claims.

III. Plaintiffs Inadequately Plead Fraud and Misrepresentation Claims (Counts V-X).

Plaintiffs also attempt to repackage their failure-to-warn claims into several fraud and misrepresentation claims: fraudulent concealment (Count V); fraudulent misrepresentation (Count VI); unfair trade practices (Count VII); negligent misrepresentation (Count VIII); strict product liability misrepresentation (Count IX); and innocent misrepresentation (Count X). These claims are subject to Rule 9(b)'s heightened pleading standard to the extent they depend on allegations of fraud, which Plaintiffs' conclusory allegations fail to satisfy. And to the extent any claims do not depend on allegations of fraud, they fail to state a claim.

The Third Circuit has explained that "all of Plaintiffs' claims alleging fraudulent activity—*i.e.*, Plaintiffs' claims for intentional and negligent misrepresentation, unjust enrichment and an injunction—must be pled with sufficient particularity under Rule 9(b)." *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85 n.3 (3d Cir. 2015) (non-precedential) (citing *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 717 (3d Cir. 1996)). Thus, Rule 9(b) applies to claims that sound in fraud, and it applies to violations of many unfair trade practice statutes. *See Gross v.*

Coloplast Corp., 434 F. Supp. 3d 245, 252-53 (E.D. Pa. 2020); *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 498 n.33 (3d Cir. 2013) (explaining that Rule 9(b) applies to fraudulent misrepresentation claims under Pennsylvania's unfair trade practice act, but not to claims under that act's catchall provision).

Since some unfair trade practice claims do not sound in fraud, and there is a division of authority in this District whether Rule 9(b) applies to negligent misrepresentation claims, Defendants also explain why these claims fail under Rule 8.

A. The Complaint Does Not Satisfy the Heightened Pleading Requirement for Fraud.

Under Rule 9(b), plaintiffs "must state with particularity the circumstances constituting fraud." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 778 (3d Cir. 2018) (quoting Fed. R. Civ. P. 9(b)). Although the elements of fraud-based claims vary, federal plaintiffs "must allege 'the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.'" *Id*. (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007), *superseded by statute on other grounds*). In other words, plaintiffs must describe "the who, what, when, where, and how" of the alleged fraud. *United States ex rel. Bookwalter v. U.P.M.C.*, 946 F.3d 162, 176 (3d Cir. 2019). "Rule 9(b)'s heightened pleading standard gives defendants notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." *In re Burlington Coat Factory*, 114 F.3d at 1418.

Here, Plaintiffs' fraud allegations are the quintessentially vague and overly generalized allegations that courts reject as failing to meet Rule 9(b). Plaintiffs claim that Defendants concealed from Plaintiffs, the medical community, and the general public "material information" relating to the alleged risks of GLP-1RAs and GLP-1RA/GIPs. Compl. ¶¶ 734-35. Plaintiffs claim

non-specific information was not included on Defendants' "promotional websites," *id.* ¶ 736, and that Plaintiffs were not warned that the medicines had been inadequately tested, *id.* ¶ 742. Plaintiffs also vaguely allege that Defendants misrepresented the long-term effects of GLP-1RAs and GLP-1RA/GIPs, *id.* ¶ 767, overstated their benefits, and "represent[ed] GLP-1 RA Products as a safe and effective treatment for diabetes with only minimal risks." *Id.* ¶¶ 772-73. Plaintiffs' unfair trade practice claims are premised on Defendants' "unfair competition or unfair, deceptive, misleading, false, fraudulent, or unconscionable acts or practices." *Id.* ¶ 751; *see also id.* ¶ 756.

These boilerplate allegations do not describe the "who, what, when, where, and how" required to meet Rule 9(b)'s heightened pleading standard. *See Gross*, 434 F. Supp. 3d at 252-53 (holding that a plaintiff's conclusory fraud-based claims against a pelvic mesh manufacturer did not meet Rule 9(b)'s heightened pleading standard). This is especially important in the pharmaceutical context, where judges have been skeptical that challenges to the safety of the medicine support a viable fraud claim. *See Bentley v. Merck & Co.*, No. 17-CV-1122, 2017 WL 2349708, at *2 (E.D. Pa. May 30, 2017) (dismissing claims where "[p]laintiffs baldly assert that defendants falsely represented to unnamed individuals, on unspecified dates, that Zostavax was safe and effective"). Like in *Bentley*, Plaintiffs here have likewise failed to "allege the date, place, time, and source of the misrepresentations," failed to "identify the specific misrepresentation in issue, or when or where they occurred," and failed to "allege[] why additional information to substantiate [Plaintiffs'] general allegations lies exclusively within the control of defendants." *Id.*

District courts routinely dismiss such vague and underdeveloped allegations of fraud. *See, e.g.*, *King v. Ethicon, Inc.*, No. 21-CV-17983, 2022 WL 2341633, at *6 (D.N.J. June 29, 2022) (explaining that courts commonly dismiss fraud and fraudulent concealment claims that allege defendant made misstatements about a product's safety and efficacy); *Blair v. Johnson & Johnson*,

No. 19-CV-333, 2020 WL 1172715, at *6 (W.D. Ky. Mar. 11, 2020) (dismissing negligent misrepresentation claim under Rule 9(b) where "[t]he complaint only mentions vague representations" that the defendants "misrepresented the safety and efficacy of the Products"); *Hernandez v. Johnson & Johnson*, No. 20-CV-5136, 2021 WL 320612, at *5 (E.D. Wash. Jan. 8, 2021) (dismissing unfair trade practice claims that were supported by defendant's general representations that certain mesh products were "safe, effective, [and] reliable").

Plaintiffs' innocent misrepresentation claim fails for the same reason. *See Smith v. Bank of Am. Corp.*, 485 F. App'x 749, 753 (6th Cir. 2012) (non-precedential) (holding that homeowners' complaint against bank for innocent misrepresentation and silent fraud, under Michigan law, failed to allege fraud with sufficient particularity required by federal rule, and thus, failed to state a claim for relief); *S. Track & Pump, Inc. v. Terex Corp.*, 623 F. Supp. 2d 558, 567 (D. Del. 2009) ("The Court agrees with Defendant that Plaintiff has not pleaded fraud and negligent or innocent misrepresentation with adequate particularity under Rule 9(b).").

Plaintiffs also fail to satisfy Rule 9(b) because they do not allege the "where" of any fraud. The Complaint identifies no specific documents in which either Novo or Lilly made any misstatements. Instead, the Complaint vaguely alleges that fraudulent statements were transmitted through "advertising campaigns, labeling materials, print advertisements, commercial media, and marketing." Compl. ¶ 768. But "general references to advertisements and statements [are not] sufficient to allege a deceptive act or practice." *Woods v. Maytag Co.*, No. 10-CV-0559, 2010 WL 4314313, at *16 (E.D.N.Y. Nov. 2, 2010); *see also Blair*, 2020 WL 1172715, at *7 (dismissing fraud-by-omission claim because "plaintiffs do not allege . . . when the alleged omission occurred" and "discuss the alleged practices only at a high level of generality"). Likewise, Plaintiffs' references to unspecified websites, *see, e.g.*, Compl. ¶ 736, do not satisfy Rule 9(b). *Hall v.*

Bristol-Myers Squibb Co., No. 06-CV-5203, 2009 WL 5206144, at *9 (D.N.J. Dec. 30, 2009) ("Plaintiffs fail to identify any specific advertisements Plaintiff [or the decedent] viewed, how they were misled by these advertisements, how these advertisements affected their prescriptions for [the medication] and how these advertisements caused any of their injuries."); *see also Sharifan v. NeoGenis Labs, Inc.*, 622 F. Supp. 3d 478, 489 (S.D. Tex. 2022) (holding that Plaintiff's "vague mention of a nebulous advertising campaign is of such a high level of generality that it fails to provide even the most minimal context so that [defendant] can identify the advertisement(s) at issue and prepare its defense accordingly"). Such vague allegations do not put Defendants on notice of the alleged fraud at issue and do not suffice to make Plaintiffs' claims plausible.[4]

Finally, the Complaint lumps the Defendants together, making it unclear which Defendant is alleged to have committed which purported "fraud." In a case involving multiple defendants, "the complaint should inform each defendant of the nature of his alleged participation in the fraud." *Silverstein v. Percudani*, 422 F. Supp. 2d 468, 473 (M.D. Pa. 2006) ("A complaint that 'lumps' together numerous defendants does not provide sufficient notice of which defendants allegedly made the misrepresentations."), *aff'd*, 207 F. App'x 238 (3d Cir. 2006) (non-precedential). Here, the Complaint broadly asserts that both Novo and Lilly made unspecified fraudulent statements and omissions. But it is implausible that Novo and Lilly made identical representations, and Plaintiffs' broadbrush assertions do not support viable fraud claims under well-established precedent.

[4] To the extent any misrepresentation claims survive, Defendants reserve the right to challenge the adequacy of any justifiable reliance allegations in the Short Form Complaints on a plaintiff-by-plaintiff basis. *Shuker*, 885 F.3d at 779 (affirming dismissal where "the complaint does not provide any details about how the press release 'induced or influenced' the surgeon's course of conduct").

Plaintiffs' fraud-based claims lack the specificity required by Rule 9(b), and thus these claims should be dismissed.

B. Counts V-X Are Inadequately Pleaded Under Rules 8 and 12(b)(6).

1. Plaintiffs Admit They Have No Support for Fraudulent Misrepresentation.

The Court should dismiss Plaintiffs' placeholder claim for Fraudulent/Intentional Misrepresentation (Count VI). Under Rule 8, a complaint must provide sufficient detail to put defendants on notice of the claims against them. *See Iqbal*, 556 U.S. at 677-78.

Conceding that they have no factual basis to allege intentional fraud, Plaintiffs' claim is "INTENTIONALLY LEFT BLANK," and they purport to "reserve the right to amend to add fraud claims after discovery." Compl. 205 n.544. At a minimum, the Court should dismiss this improper placeholder count because it contains no factual support and thus provides insufficient notice to Defendants of the alleged fraud. *See Princeton Digital Image Corp. v. Ubisoft Ent. SA*, No. 13-CV-335, 2016 WL 6594076, at *10 (D. Del. Nov. 4, 2016), *R&R adopted*, 2017 WL 6337188 (D. Del. Dec. 12, 2017) (dismissing placeholder claim).

2. Even If Not Subject to Rule 9(b), Plaintiffs' Misrepresentation Claims Are Inadequately Pleaded.

To the extent any of Plaintiffs' unfair trade practices (Count VII), negligent misrepresentation (Count VIII), strict product liability misrepresentation (Count IX), and innocent misrepresentation (Count X) claims do not depend on allegations of fraud and are thus not subject to Rule 9(b), they still fail to state a claim under Rule 12(b)(6). The alleged misrepresentations and omissions that Plaintiffs list in the Complaint are not the sort of statements that state courts find actionable, and thus should be dismissed.

This Court's decision in *Doe A.F. v. Lyft, Inc.* is instructive. In that case, the Court analyzed a plaintiff's negligent misrepresentation claim that challenged five statements made by the

defendant, a ride-share company. *Doe A.F. v. Lyft, Inc.*, No. 23-CV-3990, 2024 WL 3497886, at *8 (E.D. Pa. July 19, 2024) (Marston, J.). The Court explained that a "statement is actionable if it is quantifiable and measurable against a specific standard," whereas "exaggeration or overstatement expressed in broad, vague, and commendatory language, and general words of superiority like 'good,' 'superb,' and 'top-notch' which convey only the seller's opinion that its product is superior, constitute puffery and are not actionable." *Id.* at *7 (internal quotations and citations omitted). Applying that standard, this Court held that the defendant ride-share company's statements about "high safety standards," "maintaining high standards," and "safety for all" were puffery that could not support a claim for negligent misrepresentation. *Id.* at *8. By contrast, the defendant's specific statements that its "protective safety features are *always on*" and that it offers "*real* help from *real* humans any time day or night" were actionable because they were specific, quantifiable, and verifiable. *Id.* at *9 (emphases added). Since the plaintiff failed to allege sufficient non-conclusory facts demonstrating these statements were false, the Court dismissed the plaintiff's negligent misrepresentation claims. *Id.*

Here, Plaintiffs make generalized assertions that Defendants misrepresented the safety and efficacy of GLP-1RAs and GLP-1RA/GIPs. *See, e.g.*, Compl. ¶ 12 ("But, these patients, like Plaintiffs, were lured into a false sense of hope that GLP-1 RAs would guarantee results and be efficacious and safe."). As to the products' efficacy, Plaintiffs complain that average weight loss is modest, saying—with no context—that "[s]tudies show that the real number are [sic] much lower." *Id.* ¶ 590. However, it is unclear what "number" Plaintiffs claim was misrepresented. At bottom, Plaintiffs are asserting that the weight loss benefits of GLP-1RAs and GLP-1RA/GIPs were "overstated." *Id.* ¶ 588. As this Court explained in *Doe A.F.*, actionable misrepresentations

should be quantifiable and measurable, yet Plaintiffs here identify no such misstatements. 2024 WL 3497886, at *7-9.

Plaintiffs also broadly challenge the safety of GLP-1RAs and GLP-1RA/GIPs, but these reformulated safety-related claims are not actionable misrepresentations. Plaintiffs assert that "Defendants made continued omissions in the GLP-1 RA Products labeling, including promoting it as safe and effective while failing to warn of its propensity to cause gastroparesis." Compl. ¶ 771. But as the Third Circuit explained in *Avandia*, it is well established "that 'safe and effective' are relative terms in the pharmaceutical industry—'safe' drugs harm some people and 'effective' drugs do not work in every case." 588 F. App'x at 177 (citing *Bailey v. Wyeth, Inc.*, 37 A.3d 549, 554 n.8 (N.J. Super. Ct., Law Div. 2008); 21 C.F.R. § 201.57). Thus, broad challenges to the safety of an FDA-approved medicine do not state a viable claim.

Nor can Plaintiffs reverse course and allege that GLP-1RAs and GLP-1RA/GIPs are effective for weight loss but cause unhealthy weight loss. According to Plaintiffs, Defendants allegedly failed to disclose that patients must remain on these medications to sustain weight loss. Compl. ¶¶ 9, 592, 855. That allegation is implausible, however, because common sense dictates that a patient stops receiving the benefits of a medication when she ceases her treatment: medicines rarely provide lifetime benefits for chronic conditions. Plaintiffs then pivot to allege, repeatedly, that Defendants should have provided dietary and general nutritional advice. *Id.* ¶¶ 84-85, 603. But that claim too is implausible. Pharmaceutical manufacturers are not obligated to (and are in no position to) render such individualized medical advice; doing so could be construed as inappropriately interfering with the physician-patient relationship. Plaintiffs also contend that Defendants did not disclose that patients frequently stop taking GLP-1RAs and GLP-1RA/GIPs due to adverse events. Compl. ¶¶ 852-53. But the FDA-approved labels for various GLP-1RAs

and GLP-1RA/GIPs identify the percentage of patients who discontinued using the respective medication during clinical trials. *See, e.g.*, Ex. A, at 7; Ex. B, at 8; Ex. C, at 8; Ex. D, at 7; Ex. E, at 9; Ex. F, at 6; Ex. G, at 6; Ex. H, at 7.

Plaintiffs' claims should be dismissed because, even if some of those claims are not subject to Rule 9(b), the misrepresentations and omissions on which they are based are not actionable and thus fail to state a claim under Rule 12(b)(6).

3. Count VII Does Not Even Identify Unfair Trade Practice Claims.

In addition to the Rule 9(b) and Rule 12(b)(6) failings described above, the Court should dismiss Count VII for Unfair Trade Practices/Consumer Protection because that count fails under Rule 8. Count VII amounts to an inadequately pleaded list of statutory provisions—not even amounting to legal conclusions—that cite to the first section of unfair trade practice acts in fifty-five states and territories. Plaintiffs leave for the Court and Defendants to guess what unfair trade practices claims they are asserting, but that violates Rule 8. It is Plaintiffs' burden to identify and plead the elements of their statutory claims, rather than merely listing a hodgepodge of borderline irrelevant statutory provisions.

In *Lutz*, 49 F.4th at 327-28, the court explained that identifying the elements of a claim is fundamental to deciding a motion to dismiss. Plaintiffs' approach here, however, asks the Court to conduct a sweeping survey of more than a thousand statutory provisions in fifty-five states and territories to piece together whether any claims have been adequately pleaded. If Plaintiffs seek to litigate "Unfair Trade Practices/Consumer Protection" claims, they should identify the specific claims and plead facts that support the relevant elements. *Cf. Sweda*, 923 F.3d at 338 (explaining that plaintiffs must plausibly plead the facts supporting a statutory claim).

Count VII should be dismissed because Plaintiffs generically cite the opening provision of each statute without identifying the specific statutory claims and without pleading the elements necessary to state their claims. Plaintiffs baldly allege that Defendants "misled consumers regarding the safety risks associated with use of their GLP-1 RA Products, by overstating benefits and understating risks, and by marketing the products for uses for which the products were not approved." Compl. ¶ 751; *see also id.* ¶ 757 ("overstating benefits, marketing the products off label, and by omitting or downplaying side effects, complications and adverse events"—to physicians and consumers). Plaintiffs claim that, absent "the deceptive conduct," they would not have used a GLP-1RA or GLP-1RA/GIP. *Id.* ¶ 755. Plaintiffs simply list statutes in Paragraph 758(a)-(ccc), but they do not cite a single provision that would provide a basis for the relief that they seek on the claims they are bringing.

Even without an exhaustive recitation of all fifty-five states' and territories' statutes, it is clear that the Complaint fails to satisfy many, if not all, of the statutes they cite. For example, the first citation to Alabama law fails to note that the statute is exclusive of other claims. *Id.* ¶ 758(a) (citing Alabama Code § 8-19-1 *et seq.*); *see also* Alabama Code § 8-19-15(a) (requiring a person pursuing a claim under that statute to "exclude and be a surrender of all other rights and remedies available at common law, by statute or otherwise, for fraud, misrepresentation, deceit, suppression of material facts or fraudulent concealment arising out of any act, occurrence or transaction actionable under this chapter").

Similarly, Plaintiffs include statutes from states such as West Virginia and New Jersey that have determined that the purposes of their unfair trade practice acts are inconsistent with pharmaceutical cases, specifically physician prescriptions and FDA regulation. *See White v. Wyeth*, 705 S.E.2d 828, 837-38 (W. Va. 2010) (agreeing with *N.J. Citizen Action v. Schering-*

Plough Corp., 842 A.2d 174 (N.J. Super. Ct. 2003)). In *Sinclair v. Merck & Co., Inc.*, the New Jersey Supreme Court found that, where the crux of plaintiff's claim was that medication allegedly caused an injury, the claim needed to be brought under New Jersey's product liability act rather than an unfair trade practices claim. 948 A.2d 587, 596 (N.J. 2008).[5] Moreover, applying slightly different reasoning, the Texas Supreme Court has held that a plaintiff could not plead an unfair trade practices act claim to avoid the requirements—including the learned intermediary doctrine—of a failure to warn claim. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 169 (Tex. 2012).

Finally, some states' unfair trade practices acts do not apply to personal injury actions. *See, e.g.*, Fla. Stat. § 501.212 (Florida's Deceptive and Unfair Trade Practices Act is inapplicable to personal injury claims and does not apply when the act or practice is required or specifically permitted by federal or state law); Alaska Stat. § 45.50.531 (damages are limited to "an ascertainable loss of money or property," precluding a suit for personal injury); *Donahue v. Ledgends, Inc*., 331 P.3d 342, 353-54 (Alaska 2014) (same); *Heejoon Chng v. U.S. Bank N.A.*, 250 F. Supp. 3d 658, 691 n.28 (D. Haw. 2017); Iowa Code § 714H.2 (specifying that damages do not include damages for personal injury); 5 Maine Rev. Stat. Ann. § 213(1) (limiting damages to "loss of money or property"); *Benner v. Wells Fargo Bank, N.A.*, No. 16-CV-467, 2018 WL 1548683, at *13 (D. Me. Mar. 29, 2018) (same); Or. Rev. Stat. Ann. § 646.638 (damages limited to "ascertainable loss of money or property"); *Hamilton v. Gen. Mills, Inc.*, No. 16-CV-382, 2016 WL 4060310, at *4 (D. Or. July 27, 2016) (same); *Ambach v. French*, 216 P.3d 405, 408 (Wash. 2009) (explaining that Washington's Consumer Protection Act does not allow recovery for

[5] The New Jersey Supreme Court has clarified that a claim about a representation that is distinct from a claim about a product's warning, design, or manufacture could be brought under the consumer fraud act, as it is analogous to an express warranty. *Sun Chemical Corp. v. Fike Corp.*, 235 A.3d 145, 155-56 (N.J. 2020).

personal injury); *Sinclair*, 948 A.2d at 596; *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) (explaining that Texas unfair trade practices act does not render the learned intermediary doctrine "meaningless"), *aff'd*, 165 F.3d 374 (5th Cir. 1999).

In short, this Court should dismiss Count VII because Plaintiffs have not exercised the bare minimum of diligence to plead viable claims and put Defendants on notice of the alleged claims.

IV. Plaintiffs' Design-Defect Claims Are Barred by Conflict Preemption and, in Any Event, Are Inadequately Pleaded (Counts XI and XII).

Plaintiffs' claims alleging that all GLP-1RAs and GLP-1RA/GIPs were defectively designed—one sounding in negligence (Count XI) and one in strict liability (Count XII), as well as other stray assertions about alleged design defects in other claims[6]—are barred by federal preemption. As the Court is aware, the parties are currently in discovery and, later in this litigation, will submit briefing that addresses whether Plaintiffs' ***failure to warn*** claims are preempted—specifically, whether FDA regulations forbade Defendants from adding Plaintiffs' proposed warnings to the labels of their products. This motion focuses on an independent preemption problem with Plaintiffs' ***design-defect*** claims, which present a pure legal issue on which the Supreme Court has spoken directly: Where "state-law design-defect claims . . . place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling," those laws "are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition." *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 490 (2013). Because Defendants could not unilaterally change the design of their products, Plaintiffs' design-defect

[6] *See* Compl. ¶¶ 616-17, 625, 627-28, 643-44 (Count I); *id.* ¶¶ 651-52, 660, 662, 677-78 (Count II); *id.* ¶ 685 (Count III); *id.* ¶ 709 (Count IV); *id.* ¶ 731 (Count V); *id.* ¶¶ 750, 758 (Count VII); *id.* ¶ 782 (Count VIII); *id.* ¶ 790 (Count IX); *id.* ¶¶ 829, 834-35 (Count XIII).

claims are preempted as a matter of law.[7] And in any event, those claims are inadequately pleaded because they fail to allege facts supporting the common elements under state law.

A. Plaintiffs' Design-Defect Claims Are Barred by Conflict Preemption.

Under the Supremacy Clause, a claim is preempted if, among other things, "it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 634 (2011) (internal quotation marks omitted). As the Supreme Court has explained, in the pharmaceutical context, the touchstone of impossibility preemption is whether the defendant can ***unilaterally*** take action to satisfy state law duties without the prior approval of FDA: "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24.

The Supreme Court has held that "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition." As the Court in *Bartlett* explained: "Once a drug—whether generic ***or brand-name***—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative *formulation* of the drug product, including active ingredients, or in the specifications provided in

[7] The Court should dismiss all design-defect claims as a matter of law because they are preempted regardless of any failure-to-warn preemption. However, if the Court concludes the warnings were adequate as a matter of law or that Plaintiffs cannot prove general causation, the design-defect claims also would fail with the failure-to-warn claims. Among other things, as the Supreme Court recognized, many courts apply comment k to the Restatement "to mean that manufacturers 'did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings.'" *Bartlett*, 570 U.S. at 485.

the approved application.'" 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i), which currently refers to "inactive" ingredients) (emphasis added).

A manufacturer is barred by federal law from making a unilateral major change to an FDA-approved medication. Section 314.70(b)(1) defines major changes to include a broad array of modifications, including "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product." Section 314.70(b)(2) also lists a separate category of changes that FDA has pre-determined are "major changes." Among these enumerated major changes are any changes to the "formulation of the drug product, including inactive ingredients." 21 C.F.R. § 314.70(b)(2)(i). Moreover, a manufacturer may not make any change to the active ingredient in an FDA-approved medication without participating in a full New Drug Application (NDA) process. *Id.* § 314.70(h).

Although *Bartlett* involved a generic manufacturer, its holding and rationale apply equally to brand manufacturers. These companies likewise are prohibited from changing an FDA-approved product's design without obtaining FDA's prior approval. *See, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 289 (6th Cir. 2015) (holding plaintiff's design-defect claim against brand manufacturer was preempted); *Gustavsen v. Alcon Laby's, Inc.*, 903 F.3d 1, 10-12 (1st Cir. 2018) (holding plaintiffs' state-law claims were preempted because changing the product bottle to dispense a different amount of medication was a major change that required FDA pre-approval); *Ignacuinos v. Boehringer Ingelheim Pharms. Inc.*, 8 F.4th 98, 105 (2d Cir. 2021) (holding plaintiffs' state-law claims were preempted because a change in (1) the design of the inhaler to release a different amount of medication per puff, or (2) the amount of medication in each cartridge would

be a major change that required FDA pre-approval); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 512 F. Supp. 3d 1278, 1294 (S.D. Fla. 2021).[8]

Those principles foreclose Plaintiffs' design-defect claims here. Notwithstanding these federal regulations prohibiting design changes without prior FDA approval, Plaintiffs' Complaint asserts that GLP-1RA and GLP-1RA/GIP medications are "defective in design or formulation." Compl. ¶ 807-08 (Count XI), ¶ 819-20 (Count XII). Plaintiffs claim that the benefits of Defendants' products were outweighed by the foreseeable risks, that a safer, economically feasible alternative design existed, that Defendants' design failed to minimize and counteract the risks of known adverse effects, and that the design or formulation failed to take into consideration the proper dosage to avoid Plaintiffs' alleged injuries. *Id.* All of these claims hinge on the premise that Defendants should have designed their semaglutide, liraglutide, tirzepatide, and dulaglutide molecules differently. These design-defect claims run squarely into FDA regulations prohibiting manufacturers from "unilaterally" changing the design, formulation or chemical composition of an approved medication without FDA's approval. *Bartlett*, 570 U.S. at 490.

[8] The Third Circuit has said, in dicta, that the Supreme Court in *Wyeth* held that design-defect claims are not preempted as to brand manufacturers. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 159 n.20 (3d Cir. 2014). But the claims in *Wyeth* were for failure to warn, not design defect. *Wyeth v. Levine*, 555 U.S. 555, 558 (2009). The court's characterization in *Fosamax* appears to flow from a facet of some states' laws that permit design-defect claims to be grounded in the product's formulation *or* labeling. *See Bartlett*, 570 U.S. at 482. *Bartlett* makes clear that manufacturers may not alter the formulation of an FDA-approved product, refers to "generic ***or brand name***" medicines expressly, and is consistent with the regulatory reality that a brand manufacturer has no more ability to unilaterally change an approved drug design than a generic manufacturer. The complete inability of both generic and brand-name manufacturers to change a drug's formulation distinguishes design-defect challenges here from challenges to product labeling in *Fosamax* where brand manufacturers may unilaterally change the label in the limited circumstances permitted by the Changes Being Effected regulations. *See Wyeth*, 555 U.S. at 573. As noted, this motion does not address preemption as it relates to Plaintiffs' failure-to-warn claims, and focuses only on Plaintiffs' *design-defect* claims challenging the medicines' formulation, which the Supreme Court in *Bartlett* addressed directly.

Plaintiffs also broadly include allegations that Defendants failed to use ordinary care in manufacturing, testing, advertising, promoting, marketing, selling, and/or distributing their products. *See, e.g.*, Compl. ¶ 820 (Count XII). Whether these allegations are properly cast as design-defect claims or are simply improper redundancies of other counts in the Complaint, Plaintiffs cannot avoid preemption of their pure design-defect claims (*i.e.*, claims that go to the composition of the product itself) by muddling their design-defect counts with extraneous allegations.

Because Defendants could not unilaterally change the design of their GLP-1RA and GLP-1RA/GIP medications without FDA approval, Plaintiffs' design-defect claims are preempted by federal law and accordingly should be dismissed.

B. In the Alternative, the Design-Defect Claims Are Inadequately Pleaded.

Plaintiffs' bare-bones design-defect claims also do not satisfy the plausibility standard for federal pleading. A complaint requires more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" or "naked assertions" without "further factual enhancement." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557).

The Complaint's allegations merely track elements of claims—such as averring that all Defendants "failed to use ordinary care" and did not design the products "as to properly minimize the adverse effects on the gastrointestinal and immune systems," with benefits "greatly outweighed by the risks." Compl. ¶ 807. Plaintiffs allege that Defendants did not consider "the proper dosage that could avoid [claimed injuries]," characterizing the medicines as "more dangerous than other similar drugs." *Id.* ¶¶ 807, 810. But Plaintiffs do not identify what each Defendant allegedly did with regard to each product's design that was allegedly defective—indeed, Plaintiffs' design-defect allegations do not distinguish between the two Defendants at all. Plaintiffs likewise do not identify what medications they consider to be "similar" and whether such medications could be used interchangeably given the circumstances of the Plaintiffs' healthcare needs. Moreover,

Plaintiffs never aver that "alternate dosing and reduced exposure," *id.* ¶ 811, would have been as effective or would have avoided the alleged risks of the product.

Plaintiffs offer only conclusory, unspecified disagreement with the FDA-approved formulation, design, and dosing of these medications. To the extent that any design-defect claims escape implied preemption, this Court should dismiss them as inadequately pled.

V. Plaintiffs' Negligence Claim Is Inadequately Pleaded (Count XIII).

Plaintiffs improperly attempt to lump all of their pleaded (and unpleaded) claims into Count XIII, combining boilerplate assertions under the general heading of "negligence." This claim should be dismissed because it manages to repeat earlier claims while simultaneously making assertions (like manufacturing defect or failure-to-test) that are not actually pleaded in the Complaint and are unsupported by the facts.

"Products-liability law establishes a classic and well known triumvirate of grounds for liability: defective manufacture, inadequate directions or warnings, and defective design." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 232 (2011) (citing W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts 695 (5th ed. 1984); Restatement (Third) of Torts § 2 (1999)). Here, Plaintiffs' Count XIII does not fall into any category because, in attempting to plead everything, it pleads nothing.

This negligence claim alleges a dense laundry list of purported acts and omissions—without detailing any facts in support of the alleged negligence. For example, Plaintiffs allege that Defendants were negligent in "[m]anufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing their GLP-1 RA Products," and failing to warn of risks associated with these products. Compl. ¶ 834. Not only does this allegation confusingly combine elements of manufacturing defect, design defect, and failure to warn, but Plaintiffs also fail to allege any factual detail, such as how specific GLP-1RAs and GLP-1RA/GIPs

were inadequately tested and manufactured. *See Ramos-Soto v. C.R. Bard, Inc.*, No. 21-CV-1506, 2022 WL 1056581, at *1 (E.D. Pa. Jan. 14, 2022) (dismissing negligence claim that was supported only by conclusory allegations regarding inadequate design and manufacture); *Cerniglia v. Zimmer, Inc.*, No. 17- CV-4992, 2017 WL 4678201, at *3 (D.N.J. Oct. 17, 2017) (same).

Moreover, to the extent this negligence count challenges failure to warn, it is unclear why it is different from Count I (Failure to Warn – Negligence). This Court has discretion to strike such "redundant" material under Rule 12(f), as explained in more detail in Section IX below.

For these reasons, this Court should dismiss Plaintiffs' generic and unsupported negligence claim or, in the alternative, dismiss this claim to the extent it asserts claims besides a negligent failure to warn.

VI. Plaintiffs' Negligent Undertaking Claim Is Inadequately Pleaded (Count XIV).

Plaintiffs also bring a claim for negligent undertaking in an obvious but inadequate attempt to plead around the learned intermediary doctrine. This count should be dismissed because Plaintiffs cannot plead the generally recognized elements for such a claim and because courts have rejected negligent undertaking in the context of prescription medicines.

Under the negligent (or voluntary) undertaking doctrine, a party that voluntarily undertakes a duty must perform it with reasonable care. *See Patentas v. United States*, 687 F.2d 707, 714-15 (3d Cir. 1982). Courts have typically relied upon two Restatement provisions to define the "good samaritan" doctrine. *See id.* (interpreting federal maritime law and citing Restatement (Second) of Torts § 323 (Negligent Performance of Undertaking to Render Services), § 324A (Liability to Third Person for Negligent Performance of Undertaking)).

In this case, Plaintiffs' theory of voluntary undertaking is narrow because the Complaint asserts only that a duty existed in the context of direct-to-consumer advertisements. Plaintiffs contend that, as a result of these marketing campaigns, "Defendants voluntarily undertook the

responsibility to market their GLP-1 RAs directly to the consumer instead of solely to physicians and other health care providers." Compl. ¶ 844. In support of this claim, Plaintiffs cite to *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245, 1253 (N.J. 1999). *Id.* ¶ 845. However, the court in *Perez* did not evaluate voluntary undertaking arguments, and in any event, *Perez* is an outlier opinion that many other state courts have declined to follow.

In *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 143 (Tex. 2012), the plaintiff brought claims against a pharmaceutical manufacturer, including negligent undertaking, in a lawsuit alleging injuries caused by a prescription medication. The plaintiff argued that the learned intermediary doctrine did not apply due to the defendant's direct-to-consumer advertising, citing *Perez*. *Id.* at 152. In *Perez*, the New Jersey Supreme Court held that the learned intermediary doctrine did not provide a complete defense for a pharmaceutical manufacturer that provided adequate warnings to a physician when the company marketed directly to the plaintiff. 734 A.2d at 1246-47. Notably, *Perez* did not involve allegations of negligent undertaking. *See generally id.* The *Centocor* court rejected the plaintiff's reliance on *Perez*, explaining that "patients who seek prescription drugs based solely on [direct-to-consumer] advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient." *Centocor*, 372 S.W.3d at 163. Therefore, the court held that the learned intermediary doctrine applied to all of the claims, including negligent undertaking, and reversed the intermediate appellate court's opinion creating an advertising exception to the doctrine. *Id.* at 169. Many other courts have similarly rejected *Perez* as an outlier. *See, e.g.*, *In re Meridia*, 328 F. Supp. 2d at 812 n.19; *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007); *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 950-51 (Ariz. 2016); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 766 (Ky. 2004).

Moreover, some state courts have rejected the application of negligent undertaking in product liability cases absent unique facts that are not pleaded here. *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 226 F. Supp. 3d 557, 580 n.12 (D.S.C. 2017) ("While [Restatement] Section 323 is often applied in medical malpractice suits, Pennsylvania courts have never invoked the section 'in the context of a negligence-based products liability case." (internal quotation marks omitted)), *aff'd*, 892 F.3d 624 (4th Cir. 2018); *Moretti v. Wyeth, Inc.*, No. 08-CV-00396, 2009 WL 749532, at *3 (D. Nev. Mar. 20, 2009) (explaining that Nevada courts rejected negligent undertaking under Section 323 in product liability cases); *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 569 (E.D. Mich. 1993) (refusing to apply Section 324A in a case where pharmaceutical company did not warn the public about removal of medication from the market).

For these reasons, Plaintiffs' negligent undertaking claim should be dismissed.

VII. Plaintiffs Fail to Plead Statutorily Based Product Liability Claims That, in Some States, Are the Exclusive Means of Recovery.

In nearly half of the states, product liability actions are governed by statutory product liability acts. These product liability acts govern how plaintiffs assert claims, what theories of liability plaintiffs may allege, the defenses and exemptions that apply to manufacturers, and potential damages. In at least eleven states, moreover, the product liability acts are exclusive, meaning plaintiffs cannot bring common law claims when they allege their injuries were caused by a product. Here, the Complaint contravenes these basics of state-tort law because Plaintiffs fail to plausibly plead statutorily based product liability claims. And, in any event, under these product liability acts, some Plaintiffs would be unable to recover on the common law claims pleaded in the Complaint.

As a threshold matter, Plaintiffs cannot proceed on unpleaded product liability act claims. Eighteen states have adopted product liability acts and at least two states have enacted similar legislation.[9] Understanding at the outset what claims Plaintiffs are pleading is important because product liability statutes generally restrict, rather than expand, the theories Plaintiffs can plead. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, 2020 U.S. Dist. LEXIS 245338, at *45 (S.D. Fla. 2020) ("[E]xperience teaches that, unless cases are pled clearly and precisely, issues are not joined, discovery is not controlled, the trial court's docket becomes unmanageable, the litigants suffer, and society loses confidence in the court's ability to administer justice." (internal quotation marks omitted)). Under Rules 8 and 12, a pleading must set forth Plaintiffs' allegations and a plausible basis for relief, not ask the Court or Defendants to guess at what claims Plaintiffs intend to bring.

Here, the Complaint does nothing more than state Plaintiffs' vague "inten[t] to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act." Compl. ¶¶ 647, 681, 705, 727, 746, 749, 763, 785, 799, 812, 824, 839, 960, 868, 872, 876. Plaintiffs fail to plausibly plead statutorily based product liability claims and thus they cannot proceed on such claims.

This Court should require Plaintiffs to plead any statutorily based claims with a level of detail that gives fair notice of the claims at issue. For example, in *In re Zantac*, the personal injury

[9] Arkansas, Colorado, Connecticut, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Tennessee, Texas, Utah, and Washington. Michigan has adopted statutory provisions that pertain to products liability, but not a separate act. *See* Mich. Comp. Laws Serv. § 600.2946. Alabama applies its Alabama Extended Manufacturer Liability Doctrine to product liability cases. This issue affects approximately half of the Plaintiffs with complaints on file.

plaintiffs set forth claims in the Second Amended Master Complaint using state-specific subcounts, which allowed the Court and the defendants to have notice of which claims were at issue. *In re Zantac*, No. 20-MD-2924, Dkt. No. 3887 (S.D. Fla. Aug. 2, 2021); *see, e.g.*, *id.* ¶ 772 (Connecticut count citing Conn. Gen. Stat. § 52-572q), ¶ 1704 (Kentucky count explaining purported state law duty), ¶ 812 (Louisiana count citing La. Rev. Stat. § 9:2800.53(9)).

Plaintiffs' lack of detail eventually will cause confusion in this MDL because the product liability acts in at least eleven states either subsume some or all of the claims brought in the Complaint or set forth specific pleading requirements.[10] For example, nearly 20% of Plaintiffs with complaints on file hail from Texas or Kentucky. Under Texas law, the legislature has enacted a rebuttable presumption that a prescription medication's warnings are adequate as a matter of law. Tex. Civ. Prac. & Rem. Code § 82.007(a)(1). The presumption, which has only five narrow exceptions, applies regardless of whether a plaintiff pleads negligence, strict liability, misrepresentation, breach of warranty, "or any other theory." Tex. Civ. Prac. & Rem. Code § 82.001(2); *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 376 (5th Cir. 2012) ("Texas adopted § 82.007 as a tort reform measure, intentionally restricting certain common law claims concerning FDA-approved drugs except where such claims closely parallel the procedures and results required by the agency itself."). Similarly, Kentucky's "Products Liability Act applies to all damage claims arising from the use of products, regardless of the legal theory advanced." *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (quoting *Monsanto Co. v. Reed*, 950 S.W.2d

[10] *See, e.g.*, Conn. Gen. Stat. § 52-572m; Ind. Code Ann. § 34-20-1-1; Kan. Stat. Ann. § 60-3304(a) (Kansas provides for a rebuttable presumption for compliance with standards); La. Rev. Stat. § 9:2800.52 (Louisiana's Act "establishes the exclusive theories of liability for manufacturers for damage caused by their products."); Miss. Code Ann. § 11-1-63; *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991) (New Jersey); N.C. Gen. Stat. § 99B-1(3); Ohio Rev. Code Ann. § 2307.71(B); *Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 392 (6th Cir. 2013) (applying Tennessee law).

811, 814 (Ky. 1997)) (brackets omitted). Kentucky also has adopted a rebuttable presumption that a product is not defective if it conformed to the then-existing "generally recognized and prevailing standards or the state of the art." Ky. Rev. Stat. § 411.310(2).

This Court should require Plaintiffs to account for the impact of product liability acts because an "intent" to plead neither pleads viable claims nor accounts for the ways in which statutes impact the claims pleaded in the Complaint. The Court could do so in at least three ways: (1) dismiss the Complaint and order Plaintiffs to replead claims only as to the states that permit them, with subcounts accounting for the requirements of the products liability acts; (2) dismiss the claims that fail for the reasons set forth in this Motion and then require Plaintiffs to plead state-specific requirements for any remaining claims in their Short Form Complaints; or (3) require Plaintiffs to adopt a version of the Short Form Complaint for each of the twenty jurisdictions set forth above and authorize the Defendants to file a motion to dismiss as to each. In whatever way the Court chooses to proceed, Plaintiffs cannot merely "intend" to plead statutory claims that govern, and at times contradict, the claims contained in the Complaint.

VIII. The Court Should Dismiss Plaintiffs' Improperly Pleaded Request for Medical Monitoring Damages (Prayer for Relief).

The Court should dismiss Plaintiffs' demand for medical monitoring as a remedy. Plaintiffs' requests for medical monitoring are speculative and threadbare, falling far short of the standard for compensable injury applied by state courts. Although the requirements vary among states that recognize medical monitoring damages, Plaintiffs have not pleaded facts supporting the requirements to satisfy any state's law, much less every state.

Far from being routinely awarded, medical monitoring damages face significant hurdles. Some states require that plaintiffs plead and prove that they have already manifested a physical injury for which they are seeking future testing. *See, e.g.*, *Sinclair*, 948 A.2d at 595; *Lowe v. Philip*

Morris USA, Inc., 183 P.3d 181, 187 (Or. 2008) (affirming dismissal of smoker's negligence claim seeking recovery for medical monitoring). Likewise, some states require "a *significantly* increased risk of contracting a latent disease." *See Exxon Mobil Corp. v. Albright*, 71 A.3d 30, 78 (Md. 2013). And, as a fundamental matter, it is important that the plaintiff prove that the damages she seeks are not speculative. *See, e.g.*, *Bryson v. Pillsbury Co*., 573 N.W.2d 718, 721 (Minn. Ct. App. 1998) (holding that, to recover damages for medical monitoring, the plaintiff must show "(1) that the future harm is more likely than not to occur; and (2) that her future damages are not too speculative").

Plaintiffs here have made no effort to plead facts supporting medical monitoring damages. Instead, Plaintiffs baldly seek "the need for lifelong medical treatment, monitoring and/or medications." Compl. ¶ 587. In fact, it appears that Plaintiffs demand only damages for monitoring patients "for adverse events." *Id.* ¶ 245; *see also id.* 649 (wherefore clause) (seeking "medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries").

Plaintiffs' medical monitoring request should be dismissed because no state has authorized a damages award for such speculative, unspecified future medical tests.

IX. The Court Should Strike Plaintiffs' Assertions That the Complaint Is Not Operative (Preliminary Statement).

This Court should strike language in the Preliminary Statement saying that the Complaint is administrative and not operative. Any amended complaint should clarify that it is the Master and Short Form Complaints, in combination, that are operative for purposes of judgment and

appeal. Plaintiffs' current pleading threatens to create inefficiency and confusion in this coordinated proceeding.[11]

Under Rule 12(f), the Court has authority to strike immaterial and impertinent statements in pleadings. The Court may strike allegations to avoid the waste of resources dedicated to litigating such issues. *See Doe A.F. v. Lyft, Inc.*, No. 23-CV-3990, 2024 WL 4479912, at *3 (E.D. Pa. Oct. 10, 2024) (Marston, J.). "The purpose of a motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *Snider ex rel. Goldhirsh v. State Farm Fire & Cas. Co.*, 644 F. Supp. 3d 141, 147 (E.D. Pa. 2022) (internal quotation marks omitted). "A motion to strike is a drastic remedy to be resorted to only when required for the purposes of justice." *Doe A.F.*, 2024 WL 4479912, at *3 (internal quotation marks omitted).

One of the primary efficiencies of the MDL process is the potential resolution of dispositive issues that can narrow or eliminate categories of claims. *See, e.g.*, *In re Asbestos Prods. Liab. Litig. (No. VI)*, 718 F.3d 236, 240-41, 247-49 (3d Cir. 2013). District courts managing MDLs have broad discretion to insist that pleadings move the litigation forward in a fair and efficient manner. *See In re Deepwater Horizon*, 907 F.3d 232, 233-35 (5th Cir. 2018) (per curiam). As the Manual for Complex Litigation explains, "court and parties should take care to ensure a common understanding of the . . . intent and significance" of master pleadings. Manual for Complex Litigation § 20.132 (4th ed.).

Here, the Complaint states that it is "administrative" and not operative. Compl. 1 ("This Master Long Form Complaint . . . is not intended as the operative pleading for purposes of judgment and appeal."). These assertions undermine the Court's ability to dismiss claims with

[11] Defendants agree with Plaintiffs that no individual cases are "merged or consolidated."

any finality especially when Plaintiffs go on to contend that there is no consolidation "for any purpose." This Complaint is not merely an "administrative" statement of "common facts and potential claims," it sets forth the primary claims that Plaintiffs may bring in their Short Form Complaints and factual basis for these claims. The Complaint also allows the Court to dismiss claims and grant summary judgment on cross-cutting issue. *See, e.g.*, *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. 23-1032, 2024 WL 3423709 (3d Cir. July 16, 2024) (non-precedential) (affirming dismissal of cases with prejudice that failed to provide PCR test results).

Thus, the Court should strike the language in the Preliminary Statement that threatens to inject inefficiency into this proceeding and undermine the Court's authority.

CONCLUSION

For all of these reasons, Defendants respectfully request that the Court dismiss Plaintiffs' claims for express warranty (Count III), implied warranty (Count IV), fraudulent concealment (Count V), fraudulent misrepresentation (Count VI), unfair trade practices (Count VII), negligent misrepresentation (Count VIII), strict product liability misrepresentation (Count IX), innocent misrepresentation (Count X), design defect (Count XI and XII), negligence (Count XIII), negligent undertaking (Count XIV), and Plaintiffs' demand for medical monitoring damages.

Dated: January 24, 2025

Respectfully submitted,

/s/ Samuel W. Silver
Samuel W. Silver (PA Bar No. 56596)
Catherine M. Recker (PA Bar No. 56813)
Bruce P. Merenstein (PA Bar No. 82609)
Abigail T. Burton (PA Bar No. 334450)
Welsh & Recker, P.C.
306 Walnut Street
Philadelphia, PA 19106
Telephone: (215) 972-6430
Facsimile: (985) 617-1021
ssilver@welshrecker.com
cmrecker@welshrecker.com
bmerenstein@welshrecker.com
aburton@welshrecker.com

James F. Hurst, P.C.
Mark Premo-Hopkins, P.C.
Renee D. Smith
Diana M. Watral, P.C.
Kirkland & Ellis LLP
333 West Wolf Point Plaza
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
james.hurst@kirkland.com
renee.smith@kirkland.com
diana.watral@kirkland.com

Attorneys for Defendant Eli Lilly and Company

/s/ Loren H. Brown
Loren H. Brown
Lucas P. Przymusinski
DLA Piper LLP (US)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Telephone: (212) 335-4846
Facsimile: (212) 335-4501
loren.brown@us.dlapiper.com
lucas.przymusinski@us.dlapiper.com

Ilana H. Eisenstein (PA Bar No. 94907)
Raymond M. Williams (PA Bar No. 90771)
Rachel A.H. Horton (PA Bar No. 316482)
DLA Piper LLP (US)
1650 Market Street, Suite 5000
Philadelphia, PA 19103
Telephone: (215) 656-3300
Facsimile: (215) 606-3301
ilana.eisenstein@us.dlapiper.com
raymond.williams@us.dlapiper.com
rachel.horton@us.dlapiper.com

Matthew A. Holian
Katherine W. Insogna
DLA Piper LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110
Telephone: (617) 406-6000
Facsimile: (617) 406-6100
matt.holian@us.dlapiper.com
katie.insogna@us.dlapiper.com

Attorneys for Novo Nordisk A/S and Novo Nordisk Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 24, 2025, a true and correct copy of the foregoing Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Master Complaint was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Loren H. Brown
Loren H. Brown